

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **December 7, 2021**

AVID BIOSERVICES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction
of incorporation)

001-32839
(Commission
File Number)

95-3698422
(IRS Employer
Identification No.)

2642 Michelle Drive, Suite 200, Tustin, California 92780
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(714) 508-6100**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14A-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	CDMO	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On December 7, 2021, Avid Bioservices, Inc. (the “Company”) issued a press release to report the Company’s financial results for the second quarter ended October 31, 2021. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1. No additional information is included in this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed “filed” for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

ITEM 7.01 REGULATION FD DISCLOSURE

On December 7, 2021, at 4:30 p.m. EST/1:30 p.m. PST, the Company will host a conference call to discuss its second quarter ended October 31, 2021 financial results. The webcast of the conference call will be archived on the Company’s website for approximately 30 days.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

Exhibit Number

99.1	Press Release issued December 7, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVID BIOSERVICES, INC.

Date: December 7, 2021

By: /s/ Daniel R. Hart
Daniel R. Hart
Chief Financial Officer

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1	Press Release issued December 7, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).



Contacts:

Stephanie Diaz (Investors)
Vida Strategic Partners
415-675-7401
sdiaz@vidasp.com

Tim Brons (Media)
Vida Strategic Partners
415-675-7402
tbrons@vidasp.com

Avid Bioservices Reports Financial Results for Second Quarter Ended October 31, 2021 and Recent Developments

– Recorded Second Quarter Revenue of \$26.1 Million –

– Initiated Strategic Expansion into Viral Vector Development and Manufacturing Services for Cell and Gene Therapy –

– Signed \$36 Million in New Business Orders and Ended the Quarter with a Backlog of \$120 Million –

– Initiated Construction for Myford South Facility –

TUSTIN, Calif., December 7, 2021 -- Avid Bioservices, Inc. (NASDAQ:CDMO), a dedicated biologics contract development and manufacturing organization (CDMO) working to improve patient lives by providing high quality development and manufacturing services to biotechnology and pharmaceutical companies, today announced financial results for the second quarter of fiscal 2022, ended October 31, 2021.

Highlights Since July 31, 2021

“The second quarter was highly productive and a transformative time for Avid. The company’s financial status is increasingly strong, supported by year-over-year revenue growth, continued new business wins and a substantial backlog. Our business development team continues to perform, signing \$36 million in new business during the quarter, and ending the period with a backlog of \$120 million,” stated Nicholas Green, president and chief executive officer of Avid Bioservices.

“Leveraging the company’s strengths in quality manufacturing, regulatory compliance and customer engagement, we announced during the quarter our expansion into viral vector development and manufacturing for the cell and gene therapy market. We believe we are uniquely qualified to establish an industry-leading viral vector CDMO business, and we are actively building the team and facilities required to drive our success and expand our revenue generating capacity. Regarding mammalian cell operations, we have successfully completed our annual maintenance shutdown, completed the build-out of our second downstream processing suite in our Myford North facility, and initiated construction for the new Myford South facility. Each of these steps is an essential part of Avid’s strategy to meet the growing demand of our expanding customer base, and we continue to execute this expansion on time and on budget.

“Also during the quarter, we were pleased to have our progress, as measured in the value created for shareholders, recognized as the company’s stock was named for the first time to the S&P SmallCap 600 Index. We are honored to join this index and believe that it speaks to the collective effort of everyone at Avid, while building greater visibility for the company with investors and the industry alike. We are pleased with our recent achievements, and believe that each of the accomplishments during the quarter will facilitate growth and move us toward our overarching goal of establishing Avid as a best-in-class CDMO focused on biologics.”

Financial Highlights and Guidance

- The company is confirming revenue guidance for the full fiscal year 2022 of \$115 million to \$117 million.
- Revenues for the second quarter of fiscal 2022 were \$26.1 million, representing a 24% increase compared to \$21.1 million recorded in the prior year period. The increase in revenues can primarily be attributed to fees received from a customer during the current-year period for unutilized reserved capacity combined with an increase in process development revenues primarily associated with services provided to new customers. For the first six months of fiscal 2022, revenues were \$56.9 million, a 22% increase compared to \$46.5 million in the prior year period. The increase in revenues for the first six months of fiscal 2022 can primarily be attributed to an increase in fees received from customers for unutilized reserved capacity combined with an increase in process development revenues primarily associated with services provided to new customers.
- As of October 31, 2021, revenue backlog was \$120 million, an increase of 79% compared to \$67 million at the end of the same quarter last year. The company expects to recognize the majority of this backlog over the next twelve months.
- Gross margin for the second quarter of fiscal 2022 was 35%, compared to a gross margin of 30% for the second quarter of fiscal 2021. Gross margin for the first six months of fiscal 2022 was 36% compared to 32% for the prior year period. The increases in gross margin for the quarter and the first six months were primarily from higher manufacturing and process development revenues during the periods.
- Selling, general and administrative expenses (“SG&A”) for the second quarter of fiscal 2022 were \$5 million, an increase of 21% compared to \$4.2 million recorded for the second quarter of fiscal 2021. For the first six months of fiscal 2022, SG&A expenses were \$9.5 million as compared to \$8 million for the prior year period. The increase in SG&A during the quarter and six months was primarily due to increases in stock-based compensation, facility and related expenses and advertising costs, partially offset by a decrease in payroll and benefit related expenses.
- For the second quarter of fiscal 2022, we recorded net income attributable to common stockholders of approximately \$3.5 million or \$0.06 per basic and diluted share, as compared to net income attributable to common stockholders of \$0.8 million or \$0.01 per basic and diluted share, for the second quarter of fiscal 2021. For the first six months of fiscal 2022, the company recorded a consolidated net income attributable to common stockholders of \$9.8 million or \$0.16 and \$0.15 per basic and diluted share, respectively, compared to a consolidated net income attributable to common stockholders of \$4.5 million or \$0.08 per basic and diluted share, for the fiscal 2021 period.
- Avid reported \$163.7 million in cash and cash equivalents as of October 31, 2021 compared to \$169.9 million as of the prior fiscal year ended April 30, 2021.

More detailed financial information and analysis may be found in Avid Bioservices’ Quarterly Report on Form 10-Q, which will be filed with the Securities and Exchange Commission today.

Recent Corporate Developments

- The company announced the expansion of its CDMO service offerings into the rapidly growing cell and gene therapy market. This decision was driven by continued strong growth in this market combined with the CDMO industry’s overall lack of proven, high-quality CGMP manufacturing expertise and capacity for viral vectors. The company believes that the addition of viral vector services is a natural extension of its existing traditional biologics offering and provides another attractive avenue for growth.
- The company appointed Matthew Kwietniak as chief commercial officer with responsibility for continuing the current growth trajectory of Avid’s CDMO business through the ongoing expansion of the company’s commercial and clinical client base. Mr. Kwietniak most recently served as head of drug product sales for the Americas within the pharma services group at Thermo Fisher Scientific. In this role, he led the North America team of sales leaders and business development executives for the company’s pharmaceutical development and commercial manufacturing business.

- The company appointed Drew Brennan, an experienced CDMO business development executive, as general manager of viral vector technologies to lead the company's expansion into the cell and gene therapy market. Mr. Brennan will be responsible for overseeing all business activities related to Avid's expansion into this market. He most recently spent more than a decade in senior sales and operations positions at Novasep, a leading provider of viral vector development and manufacturing services to the cell and gene therapy market, as well as a provider of equipment and services in the fields of both small molecule production and purification for the life science and chemical industries.
 - The company appointed Elie G. Hanania, Ph.D., as vice president, process development, viral vector technologies. Dr. Hanania is a seasoned life science industry executive with more than 30 years of experience in the field of cell and gene therapy. Prior to joining Avid, Dr. Hanania most recently served as director, upstream process development for Fujifilm Diosynth Biotechnologies, where he led the process development team in charge of upstream production of all viral vectors and therapeutic proteins.
 - The company's business development team signed multiple new orders during the second quarter, totaling approximately \$36 million. These projects span all areas of the business, from process development to commercial manufacturing.
 - The two-part expansion of the Myford facility continues to progress according to plan. The first phase of the expansion, which was initiated during the second quarter of fiscal 2021, is mechanically complete, adding a second downstream processing suite to the company's existing Myford North facility. The company expects to have this equipment validated and operational in the coming months. The second phase, which was initiated during the fourth quarter of fiscal 2021, is designed to further expand capacity through the build out of a second manufacturing train, including both upstream and downstream processing suites within Myford South. During the second quarter of fiscal 2022, the new construction phase of this expansion was initiated.
- Combined, the company estimates that the first and second phases of this expansion will result in a total revenue generating capacity of up to approximately \$270 million for the mammalian cell business annually. It is anticipated that total annual revenue generating capacity will increase to approximately \$350 million with the addition of the viral vector business. While the company believes that these expansions are critical to its ability to service the future needs of its customers, Avid presently has adequate capacity to accommodate current demand.
- The company's stock (NASDAQ:CDMO), was named to the S&P SmallCap 600 Index, effective, October 29, 2021.

Statement Regarding Use of Non-GAAP Financial Measures

The company uses certain non-GAAP financial measures such as non-GAAP adjusted net income, free cash flow, as well as adjusted EBITDA. The company uses these non-GAAP financial measures for financial and operational decision making and as a means to evaluate period-to-period comparisons. The company believes that they provide useful information about operating results, enhance the overall understanding of our operating performance and future prospects, and allow for greater transparency with respect to key metrics used by management in our financial and operational decision making. These non-GAAP financial measures exclude amounts that the company does not consider part of ongoing operating results when planning and forecasting and when assessing the performance of the organization and our senior management. The company computes non-GAAP financial measures using the same consistent method from quarter to quarter and year to year, and may consider whether other significant items that arise in the future should be excluded from our non-GAAP financial measures.

The company reports non-GAAP financial measures in addition to, and not as a substitute for, or superior to, measures of financial performance prepared in accordance with U.S. generally accepted accounting principles (GAAP). These non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles, differ from GAAP measures with the same names, and may differ from non-GAAP financial measures with the same or similar names that are used by other companies. The company believes that non-GAAP financial measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP financial measures, and encourages investors to carefully consider our results under GAAP, as well as the supplemental non-GAAP information and the reconciliations between these presentations, to more fully understand our business.

Non-GAAP net income excludes stock-based compensation; business transition and related costs including corporate initiatives into new business activities such as consulting and other costs directly associated with such activities, and severance and related expenses; and non-cash interest expense on senior convertible notes for the accretion of the debt issuance costs associated with our senior convertible notes. Adjusted EBITDA excludes non-cash operating charges for stock-based compensation, depreciation and amortization as well as non-operating items such as interest income, interest expense, and income tax expense or benefit. For the reasons explained above, adjusted EBITDA also excludes certain business transition and related costs. The company also uses measures such as free cash flow, which represents cash flow from operations less cash used in the acquisition and disposition of capital.

Additionally, non-GAAP net income and adjusted EBITDA are key components of the financial metrics utilized by the company's compensation committee to measure, in part, management's performance and determine significant elements of management's compensation. The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP financial measures included at the end of this press release.

Conference Call

Avid will host a conference call and webcast this afternoon, December 7, 2021, at 4:30 PM EST (1:30 PM PST).

To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Avid Bioservices conference call. To listen to the live webcast, or access the archived webcast, please visit: <https://ir.avidbio.com/investor-events>.

About Avid Bioservices, Inc.

Avid Bioservices (NASDAQ:CDMO), an S&P SmallCap 600 company, is a dedicated contract development and manufacturing organization (CDMO) focused on development and CGMP manufacturing of biologics. The company provides a comprehensive range of process development, CGMP clinical and commercial manufacturing services for the biotechnology and biopharmaceutical industries. With 28 years of experience producing monoclonal antibodies and recombinant proteins, Avid's services include CGMP clinical and commercial drug substance manufacturing, bulk packaging, release and stability testing and regulatory submissions support. For early-stage programs the company provides a variety of process development activities, including upstream and downstream development and optimization, analytical methods development, testing and characterization. The scope of our services ranges from standalone process development projects to full development and manufacturing programs through commercialization. www.avidbio.com

Forward-Looking Statements

Statements in this press release, which are not purely historical, including statements regarding Avid Bioservices' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that the ongoing COVID-19 pandemic will adversely affect our or our customers' business and operations, the risk the company may experience delays in engaging new clients, the risk that the company may not be successful in executing client projects, the risk that the company may experience technical difficulties in completing client projects due to unanticipated equipment and/or manufacturing facility issues which could result in projects being terminated or delay delivery of products to customers, revenue recognition and receipt of payment or result in the loss of the customer, the risk that one or more existing customers terminates its contract prior to completion or reduces or delays its demand for development or manufacturing services which could adversely affect guided fiscal 2022 revenues, the risk that the completion of one or both phases of the Myford expansion and/or the viral vector facility may be delayed, may cost more than anticipated or may not increase revenue generating capacity by the amounts contemplated, the risk that expanding into a new biologics manufacturing segment may distract senior management's focus on the company's existing operations and/or its current expansion of the Myford facility, the risk that the company may experience delays in hiring qualified individuals into the viral vector business, the risk that the company may experience delays in engaging initial customers for the viral vector business, and the risk that the viral vector business may not become profitable for several years, if ever. Our business could be affected by a number of other factors, including the risk factors listed from time to time in our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2021, as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. We caution investors not to place undue reliance on the forward-looking statements contained in this press release, and we disclaim any obligation, and do not undertake, to update or revise any forward-looking statements in this press release except as may be required by law.

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(Unaudited) (In thousands, except per share information)

	Three Months Ended October 31,		Six Months Ended October 31,	
	2021	2020	2021	2020
Revenues	\$ 26,109	\$ 21,064	\$ 56,863	\$ 46,456
Cost of revenues	16,923	14,646	36,286	31,494
Gross profit	9,186	6,418	20,577	14,962
Operating expenses:				
Selling, general and administrative	5,033	4,166	9,493	7,991
Total operating expenses	5,033	4,166	9,493	7,991
Operating income	4,153	2,252	11,084	6,971
Interest and other income, net	73	32	149	47
Interest expense	(704)	–	(1,407)	(4)
Net income	\$ 3,522	\$ 2,284	\$ 9,826	\$ 7,014
Comprehensive income	\$ 3,522	\$ 2,284	\$ 9,826	\$ 7,014
Series E preferred stock accumulated dividends	–	(1,442)	–	(2,523)
Net income attributable to common stockholders	\$ 3,522	\$ 842	\$ 9,826	\$ 4,491
Net income per share attributable to common stockholders:				
Basic	\$ 0.06	\$ 0.01	\$ 0.16	\$ 0.08
Diluted	\$ 0.06	\$ 0.01	\$ 0.15	\$ 0.08
Weighted average common shares outstanding:				
Basic	61,414	56,660	61,276	56,592
Diluted	63,602	57,248	63,606	57,073

AVID BIOSERVICES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited) (In thousands, except par value)

	October 31, 2021	April 30, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 163,675	\$ 169,915
Accounts receivable, net	18,137	18,842
Contract assets	3,420	6,112
Inventory	20,310	11,871
Prepaid expenses	1,377	1,064
Total current assets	206,919	207,804
Property and equipment, net	52,496	37,455
Operating lease right-of-use assets	38,223	18,691
Other assets	3,639	1,210
Restricted cash	350	350
Total assets	\$ 301,627	\$ 265,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,005	\$ 9,257
Accrued payroll and related costs	5,053	8,794
Contract liabilities	51,865	50,769
Current portion of operating lease liabilities	1,378	1,355
Other current liabilities	1,227	761
Total current liabilities	69,528	70,936
Convertible senior notes, net	139,066	96,949
Operating lease liabilities, less current portion	39,664	19,889
Finance lease liabilities, less current portion	2,264	—
Total liabilities	250,522	187,774
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized; no shares issued and outstanding at October 31, 2021 and April 30, 2021, respectively	—	—
Common stock, \$0.001 par value; 150,000 shares authorized; 61,552 and 61,069 shares issued and outstanding at October 31, 2021 and April 30, 2021, respectively	62	61
Additional paid-in capital	600,266	637,534
Accumulated deficit	(549,223)	(559,859)
Total stockholders' equity	51,105	77,736
Total liabilities and stockholders' equity	\$ 301,627	\$ 265,510

AVID BIOSERVICES, INC.

ITEMIZED RECONCILIATION BETWEEN GAAP AND NON-GAAP FINANCIAL MEASURES

(Unaudited) (In thousands)

	Three Months Ended October 31,		Six Months Ended October 31,	
	2021	2020	2021	2020
GAAP net income attributable to common stockholders	\$ 3,522	\$ 842	\$ 9,826	\$ 4,491
Stock-based compensation	1,942	1,025	3,241	1,755
Business transition and related costs	451	4	937	212
Non-cash interest expense	255	–	509	–
Preferred stock accumulated dividends	–	1,442	–	2,523
Adjusted net income	\$ 6,170	\$ 3,313	\$ 14,513	\$ 8,981
GAAP net income attributable to common stockholders	\$ 3,522	\$ 842	\$ 9,826	\$ 4,491
Depreciation and amortization	1,027	854	2,036	1,684
Interest expense and interest income	631	(32)	1,258	(43)
Stock-based compensation	1,942	1,025	3,241	1,755
Business transition and related costs	451	4	937	212
Preferred stock accumulated dividends	–	1,442	–	2,523
Adjusted EBITDA	\$ 7,573	\$ 4,135	\$ 17,298	\$ 10,622
GAAP net cash provided by operating activities	\$ 10,603	\$ 10,406	\$ 3,661	\$ 8,133
Purchase of property and equipment	(7,625)	(2,491)	(11,824)	(2,980)
Free cash flow	\$ 2,978	\$ 7,915	\$ (8,163)	\$ 5,153

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